

**REMARKS**

This amendment responds to the objections to the claims and specification made by the Examiner in the final Action and adopts the amendments suggested by the Examiner. Accordingly, the only rejection that remains is the obviousness rejection over Chopra, U.S. Patent 6,300,377, in view of Stedman's Medical Dictionary, The Merck Index, and Drug Facts and Comparisons.

At page 6 of the final rejection the Examiner accurately expressed the differences between the Chopra reference and the presently claimed subject matter. Item (ii) was "the express proviso that alpha-lipoic acid and acetyl-L-carnitine are not administered together as recited in present claim 1." In support of that rejection the Examiner states "... the compositions disclosed by Chopra expressly recite the use of bioactive agents, including N-acetyl cysteine, alpha-lipoic acid (thioctic acid), acetyl-L-carnitine, resveratrol, or mixtures thereof". The Examiner further states:

Such statement clearly provides for any combination of at least two of the bioactive agents listed above, including all possible combinations wherein alpha-lipoic acid and acetyl-L-carnitine are not administered in the same supplement. Thus, the Chopra reference is considered to meet the limitation of "with the proviso that the composition lipoic acid and acetyl-L-carnitine are not administered together".

The Applicant respectfully traverses this basis for the rejection. It is respectfully submitted that the quoted recitation of Chopra would not render obvious all possible combinations wherein alpha-lipoic acid and acetyl-L-carnitine are not administered in the same supplement. Invention could certainly lie in the discovery that the avoidance of administration of two of the bioactive agents in the same supplement has a previously unknown advantage. The Chopra reference would not suggest to one of ordinary skill in the art that there may be particular therapeutic

advantages in avoiding administering the alpha-lipoic acid and the acetyl-L-carnitine together. All of the claims of the application include this limitation which is not disclosed or suggested by the cited art.

With regard to the differences between the Chopra reference and the presently claimed subject matter set forth by the Examiner at (v), i.e. "the particular dosage amounts as recited in the present claims or the use of synergistic effective amounts as recited in present claim 20," the Examiner states at page 9:

The Examiner acknowledges that the disclosure of Chopra does not expressly teach the particularly claimed dosage amounts of the present claims. However, the determination of optimum dosage regimen, especially that used to promote cognitive or auditory function with the presently claimed active agents, would have been a matter well within the purview of one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

The Applicant respectfully traverses this basis for rejection. It is respectfully submitted that the Examiner is expressing the concept that no invention can lie in the choice of a particular optimum dosage reference to promote cognitive or auditory function. Certainly the history of medical science is replete with examples wherein a particular choice of dosages has resulted in unexpected results. The particular dosages expressed in the present claims resulted from

extensive experimentation and the application of expertise, and there is no basis for deeming the specific dosages set forth in the claims as obvious in view of the cited references.

As the Federal Circuit has stated:

the [E]xaminer can satisfy the burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.

*In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002), citing *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). “Mere ... conclusory statements, however, are not sufficient to establish a genuine issue of material fact.” *In re Dembiczak*, 175 F.3d 994, 995, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Reconsideration and allowance are accordingly respectfully solicited.

Respectfully submitted,



Allen M. Krass  
Registration No. 18,277  
Gifford, Krass, Groh, Sprinkle,  
Anderson & Citkowski, P.C.  
2701 Troy Center Drive, Suite 330  
P.O. Box 7021  
Troy, MI 48007-7021  
(248) 647-6000

Attorney for Applicant

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Janice Burkhardt  
Janice Burkhardt